REMARKS

A necessary change is made in the specification.

The claims previously in the case have been replaced by a set of new claims which are believed to be proper as to form and clearly patentable over the cited references.

The new claims are drawn to a biological prosthesis which is an animal aortic valve with attached intraparietal reinforcement device or devices.

This invention replaces, among other things, the stented prostheses of the prior art. The stented prostheses and their drawbacks are described in our specification, page 2, down through the fourth from last line. As is pointed out there, the presence of a stent in such a prosthesis reduces the space that is available for the replacement valve relative to the original human valve, by the surface area of the circumference that is occupied by the stent. As a result, the pressure gradient in the replacement valve is artificially increased by the presence of the stent.

Unstented biological prostheses, on the other hand, are unsuitable for the reasons set forth in the material bridging pages 2 and 3 of our specification, namely, among other reasons, because implantation is very difficult.

In sharp contrast, however, the present invention combines the advantages of stented and unstented biological prostheses, to produce a biological prosthesis that enjoys the

stiffness of a stented prosthesis but which at the same time provides maximum surface area and available volume, and is simple, quick and easy to implant.

In short, the present invention embodies the best of both worlds, without their disadvantages.

The present invention does this, by using a whole animal aortic valve, which is stiffened in a special way by a new intraparietal reinforcement device in the form of a rod. The rod is implanted at the tubular wall of the animal aortic valve parallel to the direction of blood flow. There is thus no reduction of volume or area for blood flow, and hence no increase of pressure gradient in the replacement valve compared to an unstented biological prosthesis. At the same time, the aortic valve is sufficiently stiffened for easy implantation.

Preferably, the intraparietal reinforcement device is implanted at the juncture of a commissure of the aortic valve with the outer tubular wall thereof, and hence parallel to the plane of the commissure. Because there are three commissures, there are preferably three such intraparietal reinforcement devices. They are spaced apart from each other, which preserves the flexibility of the aortic valve without increasing the difficulty of implantation thereof, and they are parallel to each other.

This basic construction is set forth in new claims 21-26. Details of the structure of the intraparietal reinforcement device are set forth in the remaining claims.

Not only is the basic biological prosthesis novel and unobvious, but also, because there was never such an intraparietal reinforcement device, the various structural features of the intraparietal device, set forth in claims 27-35 are also novel and unobvious.

Reconsideration is accordingly respectfully requested, for the rejection of the claims as anticipated by or unpatentable over DZEMESHKEVICH et al., alone or in view of LOVE or MCGUCKIN, JR. or ARRU et al.

These rejections fall down on DZEMESHKEVICH et al. In this basic reference, a construction is disclosed which is even more remote from the present invention than the stented prostheses described in the introductory portions of our specification. This is because, in the basic reference, there is a closed circular framework on which bits and pieces of plural aortic valves are assembled. The basic reference thus discloses what might be considered to be the worst of all worlds. In the basic reference, the supporting structure, of general stent configuration, is covered both inside and outside with biological tissues assembled from at least two different origins of cusps taken from two different animals, which are stitched together,

and at least two other biological tissues are used to form internal and external walls of the prosthetic valve.

By contrast, the biological valve of the present invention retains fully the integrity and the functionality of the mobile elements of the natural valve, that is, the cusps and commissures.

Worse still, the basic reference provides a constriction which, as pointed out above, leads to markedly increased pressure gradient, as compared to the present invention or an unstented aortic valve.

The secondary references may teach the features for which they were cited, but as they do nothing to remedy the fundamental defects of the basic reference, enumerated above, it is not believed to be necessary to discuss the secondary references at this time.

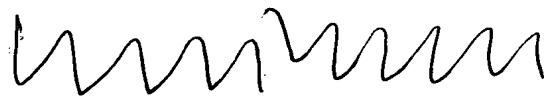
As the new claims are believed to bring out the above distinctions with ample particularity, it is believed that they are all patentable, and reconsideration and allowance are respectfully requested.

The Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any

overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

YOUNG & THOMPSON



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